DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, FL 32809

M358M

CERTIFIED LETTER
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-97-52

April 24, 1997

Mr. Brett J. Phillips
President
Phillips Pharmatech Labs Inc.
8767 115th Ave N.
Largo, Florida 34643

Dear Mr. Phillips:

During an inspection of your facility located in Largo, Florida on December 30, 1996 through February 13, 1997, FDA Investigator Shari J. Hromyak determined that you manufacture and repackage various OTC drug products, which products are human drugs within the meaning of section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act).

The inspection revealed that these drugs are adulterated within the meaning of section 501(a)(2)(B) of the Act in that they are drug products and the methods used in, or the facilities or controls used for, their manufacture, processing, packing or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice (GMP) regulations for drugs specified in Title 21, Code of Federal Regulations (CFR), Part 211 as follows:

> Failure to document, perform, or assure performance of finished product testing on each batch of product manufactured or repacked prior to release for distribution, such testing to include identity and strength of each active ingredient;
>
> Failure to establish finished product specifications for all products manufactured or repacked;
>
> An on-going, well controlled stability program has not been established, nor have stability studies been performed on all products;
>
> Expiration dates placed on Arth-Rx are not supported by adequate stability studies;
>
> Failure to perform process validation studies on various systems or to assure that such studies have been performed, including but not limited to the water system and cleaning validation procedures;

Failure to establish and maintain master production records for products manufactured or repacked;

Failure to maintain adequate batch records for manufactured or repackaged products;

Failure to establish complaint handling procedures;

Failure to establish or implement an adequate label control system, for example, labels for Arth-Rx were received, accepted and used even though lidocaine was not listed as an active ingredient; and,

Water quality specifications have not been established for deionized water used in the formulation of liquid drug products.

For your information, it is your responsibility as a drug manufacturer to assure that all requirements of the GMP Regulations pertaining to the manufactured lot (or, in the case of repacked products, those requirements that pertain to repackaging operations) are met. These include both finished product and stability testing, process validation, and assuring that all necessary records are prepared, are accurate, and are accessible both to you and the FDA. Your responsbility exists whether the procedure is performed by you or by a firm contracted to perform such procedures, and cannot be relinquished.

These deficiencies are similar and, in some cases, identical to deficiencies observed during an inspection of your firm in September 1995, demonstrating a continuing pattern of non-compliance with GMP Regulations. We refer you to the List of Observations left with your firm at the close of that inspection as well as this one. Copies of both FDA-483's are enclosed for your convenience.

This letter is not intended to be an all-inclusive list of deficiencies at your facility, nor does it cover any issues other than those involving GMP's. It remains your responsibility to ensure adherence to all requirements of the Act and regulations.

You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to seizure, injunction, and/or civil penalties.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these violations and to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time within which corrections will be completed.

Your response should be sent to the Food and Drug Administration, Florida District Office, 7200 Lake Ellenor Drive, Orlando, Florida 32809, Attention: Martin E. Katz, Compliance Officer, telephone no. (407) 648-6823, ext. 267.

Sincerely,

for Douglas D. Tolen
Director, Florida District

Enclosures